



UNITED STATES PATENT AND TRADEMARK OFFICE

SM
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 09/344,526 | 06/24/1999 | MARK S. CHEE | A-66828-2/DJ | 9163 |
| 32940 | 7590 | 06/03/2004 | EXAMINER | |
| DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 4 EMBARCADERO CENTER SUITE 3400 SAN FRANCISCO, CA 94111 | | | | MARSCHEL, ARDIN H |
| ART UNIT | | PAPER NUMBER | | |
| | | 1631 | | |
| DATE MAILED: 06/03/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/344,526 | CHEE ET AL. | |
| | Examiner Ardin Marschel | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-20, 45,46,52,53,55, and 58-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 16-20 is/are allowed.
- 6) Claim(s) 45,46,52,53,55 and 58-65 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 2/19/04, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, however, the following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

VAGUENESS AND INDEFINITENESS

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 depends from canceled claims 56 and 57 thus causing claim 65 to be vague and indefinite as to what limitations are included therein.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45, 46, 52, 53, 55, and 58-65 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-39 of copending Application No. 09/748,706; in view of Walt et al. (P/N 6,023,540). This rejection is maintained and reiterated from the previous office action, mailed 2/5/04, as not being argued.

This is a provisional obviousness-type double patenting rejection.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45, 46, 52, 53, 55, 59-62, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (P/N 6,023,540).

In the abstract Walt et al. describes the invention therein as being directed to microsphere-based chemistry carrying different functionalities as well as optically

interrogatable encoding schemes. Figure 3 of Walt et al. depicts the multiple bead invention therein with different analyte ligands (first and second decoder binding ligands as in instant claim 45, part b)) being detectable shown as 62a, 62b, and 62c with encoding schemes on the microspheres shown via different dye ratios on each bead (that is, microsphere) type. In column 11, line 25, through column 15, line 40, optical fiber sensor practice is set forth wherein the encoded beads are placed randomly on fiber optic fibers with a density of approximately 20,600 bead/fiber combinations per approximately 1 square millimeter (1 millimeter fiber optic bundle) as described in column 12, lines 16-20. A particular Genosensor type of such a sensor is described in column 15, lines 16-40, wherein different dye ratios are utilized to detect fluorescein labeled analytes directed to rabbit, goat, and mouse antibody ligands thus comprising at least first and second subpopulations of different bioactive agents as required, for example, in claim 45, part a), subpart ii). Rabbit IgG – fluorescein conjugate shows where beads with xrabbit antibody are located for decoding. Since the invention of Walt et al. is directed to multiple analyte detection in said Figure 3 and related description, this suggests that decoding the goat and mouse bead locations in the fiber optical bundle would reasonably be suggested, motivated, and performed analogously to the rabbit IgG location decoding.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to decode the bead locations on fiber optical fiber bundles with different first bioactive agents thereon for any of the antibody – bead – dye ratio locations to result in the practice of the above listed instant claims. It is noted that the

above listed instant claims lack any limitation as to what decoder ligand labels are utilized thus being inclusive of the above Walt et al. decoding which apparently utilizes the same label for decoding the different bioactive reagent locations, that is, fluorescein as in the example in column 15. Instant claim 46 is included as rejected hereinunder because the labels that decode the binding ligands are different molecules albeit of the same chemical, that is, fluorescein. It is noted that two fluorescein molecules are different entities, albeit of the same type of chemical. By way of exemplary explanation the parents of identical twin children would still view each child as a different child from the other. Instant claim 46 does not define any specific difference corresponding to what is meant by "different" in the phrase "different labels". The bioactive agent that is present on the microsphere for binding to a sample agent with label, such as fluorescein in antibody/antigen in the above example, however, a variety of other bioactive agents with their corresponding targets are also alternatively suggested in Walt et al. in column 9, line, 60, through column 10, line 16, plus in TABLE V to include well known nucleic acid probes and targets as also instantly claimed and rejected hereinunder.

Claims 45, 46, 52, 53, 55, and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (P/N 6,023,540); taken in view of Bamdad et al. (P/N 6,197,515).

The basic invention description as suggested and motivated as summarized above in Walt et al. is directed to a method of decoding an array of microspheres and is reiterated here. Walt et al. suggests and motivates a variety of bioactive agents on the microspheres which may be decoded via binding reactions with decoder binding ligands

including nucleic acid bioactive agents and nucleic acid decoder binding ligands. Walt et al., however, does not specifically describe double stranded nucleic acid bioactive agents as required in instant claim 63. This rejection is directed to such double stranded bioactive reagent embodiments in the above listed instant claims.

Bamdad et al. suggests and describes biochemical analyses which are based on a variety of binding species in column 1, lines 26-40, which are reasonably interpreted as bioactive agents with their respective binding ligands as in Walt et al. Bamdad et al. also cites the immobilization of binding agents on a surface in such analyses in said column 1 citation. Included in the usable binding agents are single and double stranded nucleic acids as options for such analyses as described in Bamdad et al. in column 17, lines 26-48, for the binding of binding partners inclusive of proteins etc. Thus, Bamdad et al. suggests and motivates either single or double stranded nucleic acid bioactive or binding partners which is deemed to suggest and motivate the instant claim 63 double stranded nucleic acid bioactive agents in binding analyses as in Walt et al.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to decode the bead locations on fiber optical fiber bundles with different first bioactive agents thereon for any of the antibody – bead – dye ratio locations to result in the practice of the above listed instant claims given the Walt et al. descriptions of such assay methodologies with the optional double stranded nucleic acid type of bioactive agent as a binding partner in such assays as suggested and motivated by Bamdad et al. to result in a reasonable expectation of success of performing the double stranded nucleic acid bioactive embodiments of the instant claims.

Claims 16-20 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 28, 2004

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
5/28/04